PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference 002441.00169	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/US2005/027239	International filing date *(day/month/year)* 29 July 2005 (29.07.2005)	Priority date *(day/month/year)* 29 July 2004 (29.07.2004)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant NOVARTIS VACCINES AND DIAGNOSTICS INC.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☒	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 16 September 2008 (16.09.2008)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Athina Nickitas-Etienne e-mail: pt04.pct@wipo.int

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing (*day/month/year*)	25 AUG 2008
Applicant's or agent's file reference 002441.00	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date (*day/month/year*)	Priority date (*day/month/year*)
PCT/US05/27239	29 July 2005 (29.07.2005)	29 July 2004 (29.07.2004)

International Patent Classification (IPC) or both national classification and IPC

IPC: **A61K 39/02**(2006.01)
USPC: 424/190.1

Applicant

CHIRON CORPORATION

1. This opinion contains indications relating to the following items:

- ☒ Box No. I — Basis of the opinion
- ☐ Box No. II — Priority
- ☐ Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV — Lack of unity of invention
- ☒ Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI — Certain documents cited
- ☐ Box No. VII — Certain defects in the international application
- ☒ Box No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis(b)* that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	21 May 2008 (21.05.2008)	PADMA v. BASKAR Telephone No. 571-272-1600

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/27239

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

☒ the international application in the language in which it was filed

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ on paper

☐ in electronic form

c. time of filing/furnishing

☐ contained in the international application as filed.

☐ filed together with the international application in electronic form.

☐ furnished subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:
   - ☒ paid additional fees
   - ☐ paid additional fees under protest and, where applicable, the protest fee
   - ☐ paid additional fees under protest but the applicable protest fee was not paid
   - ☐ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
   - ☐ complied with
   - ☒ not complied with for the following reasons:

   See the lack of unity section of the International Search Report(Form PCT/ISA/210)

4. Consequently, this opinion has been established in respect of the following parts of the international application:
   - ☐ all parts.
   - ☒ the parts relating to claims Nos. claims 1-7 and 17-24

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
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Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims NONE	YES
	Claims 1-7 and 17-24	NO
Inventive step (IS)	Claims NONE	YES
	Claims 1-7 and 17-24	NO
Industrial applicability (IA)	Claims 1-7 and 17-24	YES
	Claims NONE	NO

2. Citations and explanations:

Claims 1-7 and 17-24 lack novelty under PCT Article 33(2) as being anticipated by Telford et al .

Telford et al disclose a composition comprising two or more proteins (see page 3057, line 28, abstract) , said proteins are useful for immunogenic composition. The art discloses polypeptide SEQ.ID.NO: 80 (GBS 80, see page 1411, line 55) and is interpreted to be a first GBS AI polypeptide and polypeptide SEQ.ID.NO:3756 (GBS 67, see page 1353 line 45) is interpreted to be a second GBS AI polypeptide and said first and second adhesion polypeptide are not the same and thus read on claims 1-7 and 17,20 , 21 and 22 . First adhesion polypeptide SEQ.ID.NO: 80 (GBS 80) and second adhesion polypeptide SEQ.ID.NO:3756 (GBS 67) are from Group B *Streptococcus agalactiae* , which is a gram positive bacteria and therefore read on claims 23 and 24 . Thus the prior art anticipated the claimed invention.

Claims 1-7 and 17-24 lack novelty under PCT Article 33(2) as being anticipated by Larsson et al Vaccine ; Vol17, Issue 5, February 1999, Pages 454-458.

Larsson et al disclose an immunogenic composition (i.e., vaccine, see page 455, left column, 2.2, second para, last 6 lines) comprising GBS (i.e., *S.agalactiae* is Group B *Streptococcus*) adhesion polypeptide Rib and α as shown in figure 1 A. Polypeptide Rib and polypeptide α are reasonably interpreted to be first and second GBS AI polypeptide and thus read on claims 1-7 and 17. In the absence identifying characteristics of GBS AI polypeptide encoded by GBS AI -1 or GBS AI -2 , GBS Rib and GBS α are reasonably interpreted to be first and second GBS AI polypeptides and are encoded by GBS AI -1 or GBS AI -2 and thus meet the limitations of claims 18-19. The polypeptide Rib and polypeptide α are not same and thus they are reasonably interpreted to be first and second GBS AI polypeptides and read on claims 20-22. The same immunogenic composition reads on claims 23 and 24 as polypeptides are from gram positive bacteria, *Streptococcus*. Thus the prior art anticipated the claimed invention.

Claims 1-7 and 17-24 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/27239

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claims 1-7 and 17-24 objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims are indefinite for the following reason(s):

Claims 1-7 and 17 -24 are indefinite in reciting "Group B Streptococcus (GBS) adhesion island (AI) polypeptide" in claims 1, 17 and reciting "GBS AI polypeptide" "GBS AI-1" and ""GBS AI-2" in claims 2-6, 18-22 and reciting "adhesion island (AI) polypeptide" in claim 23. This appear to be a lab designation for adhesion polypeptide. Since this is merely a lab designation, such terminology change from lab to lab or the same designation can be used for totally different polypeptide. As such, the skilled artisan would not know the metes and bounds of the recited adhesion island (A1) polypeptide. This rejection can be overcome by amending the claims to specifically and uniquely identify polypeptide" adhesion island (A1) polypeptide", for example, by SEQ ID numbers.

Claims 4, 5, 20, 21 and 22 are indefinite in reciting "GBS 80" and GBS 67". These relative terms in claims renders the claim indefinite. It appear to be a lab designation polypeptide. Since this is merely a lab designation, such terminology change from lab to lab or the same designation can be used for totally different polypeptide. As such, the skilled artisan would not know the metes and bounds of the recited "GBS 80, "GBS 67". This rejection can be overcome by amending the claims to specifically and uniquely identify polypeptide "GBS 80, GBS 67", for example, by sequence identification numbers.

Claims 18 and 19 indefinite in reciting "encoded by a GBS AI-1" " encoded by a GBS AI-2" It appear to be a lab designation for nucleic acid Since this is merely a lab designation, such terminology change from lab to lab or the same designation can be used for totally different nucleic acid. As such, the skilled artisan would not know the metes and bounds of the recited GBS AI-1 and GBS AI-2 This rejection can be overcome by amending the claims to specifically and uniquely identify nucleic acid ""GBS 80" and " GBS 67"", for example, by SEQ sequence identification numbers.